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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,412	04/13/2004	Gianni Pasqualini	2031-043918	3241
<div>7590      10/31/2007</div> <div>William H. Logsdon WEBB ZIESENHEIM LOGSDON ORKIN &amp; HANSON, P.C. 700 Koppers Building 436 Seventh Avenue Pittsburgh, PA 15219-1818</div>				
			<div>EXAMINER</div> <div>KIM, SUN U</div>	
			<div>ART UNIT</div> <div>1797</div>	<div>PAPER NUMBER</div>
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/823,412	<b>Applicant(s)</b> PASQUALINI, GIANNI	
	<b>Examiner</b> John Kim	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 14 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-14, 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. Newly submitted claims 21-24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Group III) Claims 21-24 are directed to a blood treatment method using a carbon dioxide removing means comprising a filtering means connected between a first inlet and a first outlet.

Inventions I (original claims 1-14) and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another and materially different apparatus such as a separate carbon dioxide removing means and filtering means.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

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(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-11, 13-14 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New recitation of “the drain channel being (directly) connected to the first inlet of the CO<sub>2</sub> removing means to supply the diluting liquid (to the CO<sub>2</sub> removing means) without submitting the diluting liquid to any filtering treatment during passage along the drain channel” in independent claims 1 and 14 is new matter and does not have basis in the specification.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 9-11, 13 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porro et al (EP 0890368 A1) in view of Davidner et al (US 2002/0077581 A1).

Porro et al teach a blood treatment unit comprising oxygenator i.e. CO<sub>2</sub> removing means (B1) having a first inlet (160b) and a first outlet (160a) and hemoconcentrator i.e. filtering means (A1) having a first inlet (160a) and a first outlet (150a) wherein oxygenator and hemoconcentrator are integrated to form in one body (see Fig. 8-10; col. 6, lines 11-17; col. 8, line 54 – col. 9, line 39).

Claims 1-2 essentially differ from the device of Porro et al in reciting that a drain channel of the filtering means is directly connected to the first inlet of CO<sub>2</sub> removing means. Davidner et al teach a blood treatment device comprising a blood filter (106) with a drain channel (158) for ultrafiltrate connected to a blood inlet of oxygenator (104) i.e. CO<sub>2</sub> removing means via 109, 111, 161 to provide diluent to blood (see paragraphs 0029-0030, 0034-0035, 0038). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the blood treatment device of Porro et al to connect a drain channel of the filtering means to the first inlet of CO<sub>2</sub> removing means to provide ultrafiltrate as a diluent to blood to reduce hematocrit as suggested by Davidner et al (see paragraph 0029). Recitation of “to supply the diluting liquid without submitting the diluting liquid to any filtering treatment during passage along the drain channel” is an intended use of the apparatus.

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It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Regarding claim 3, Porro et al teach that the first outlet (160a) of oxygenator (B1) is connected to the first inlet (160a) of hemoconcentrator (A1) (see Fig. 8-9).

Regarding claim 9-10, Porro et al teach that oxygenator (B1) and the hemoconcentrator (A1) are housed in respective separate casings that are joined and fixed rigidly to each other (see Fig. 7-8).

Regarding claim 11, Porro et al teach that the hemoconcentrator (A1) project outwards from the oxygenator (B1) (see Fig. 8-9).

Regarding claim 13, Porro et al teach the oxygenator (B1) having a gas inlet i.e. 2<sup>nd</sup> inlet and gas outlet i.e. 2<sup>nd</sup> outlet (see Fig. 8-9).

Regarding claim 25, Davidner et al teach a pump (110, 114) connecting to a drain channel (158) to the blood inlet of oxygenator (104) i.e. CO<sub>2</sub> removing means via 109, 111, 161 (see paragraphs 0029-0030, 0034-0035, 0038). Pump is an obvious means to facilitate transporting of fluid from one location to another and would have been obvious to a person of ordinary skill in the art to modify the apparatus of Porro et al to include pump to move ultrafiltrate to the first inlet of CO<sub>2</sub> removing means.

6. Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porro et al in view of Davidner et al as applied to claim 2 above, and further in view of Linker et al (US 2002/0176798 A1). Porro et al in view of Davidner et al teach a blood treatment device as described in above paragraph 5. Claims 4 and 6-8 essentially differ from the device of Porro et

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al in view of Davidner et al in reciting CO<sub>2</sub> removing means comprising an inner seat housing filtering means (claim 4), filtering means comprising a second casing housed inside the first casing and housing membranes (claim 6), membranes for removing CO<sub>2</sub> interposed between the first and second casing (claim 7) and a container interposed between the membranes for removing CO<sub>2</sub> and the second casing and internally defining the inner seat (claim 8). Linker et al teach a blood treatment device having a compact size and low surface area and reducing contact between the blood and foreign surfaces to reduce priming volume, hemolysis and platelet activation (see paragraph 0010). To achieve such compact blood treatment device, Linker et al teach a housing structure including CO<sub>2</sub> removing means (70) comprising an inner seat (see central shoulder section at the bottom of filter (59) in Fig. 3) housing filtering means, filtering means (59) comprising a second casing (see casing holding filter (59) in Fig. 3) housed inside the first casing (see outer casing in Fig. 3) and housing membranes (59), membranes (70) for removing CO<sub>2</sub> interposed between the first and second casing and a container (see central shoulder section at the bottom of filter (59) in Fig. 3) interposed between the membranes for removing CO<sub>2</sub> (70) and the second casing (see casing holding filter (59)) and internally defining the inner seat (see 0048-0053, 0055-0058). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the blood treatment device of Porro et al in view of Davidner et al to include above claimed structures to integrate known blood oxygenators, blood pumps and blood filters into a single housing as suggested by Linker et al (see paragraph 0048) and make the device compact having low surface area to reduce priming volume, hemolysis and platelet activation (see paragraph 0010).

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7. Claims 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Porro et al in view of Davidner et al and Linker et al.

Porro et al teach a blood treatment unit comprising oxygenator i.e. CO<sub>2</sub> removing means (B1) having a first inlet (160b) and a first outlet (160a) and hemoconcentrator i.e. filtering means (A1) having a first inlet (160a) and a first outlet (150a) wherein the first outlet (160a) of the oxygenator is connected to the first inlet (160a) of the hemoconcentrator and oxygenator and hemoconcentrator are integrated to form in one body (see Fig. 8-10; col. 6, lines 11-17; col. 8, line 54 – col. 9, line 39).

Claim 14 essentially differ from the device of Porro et al in reciting that a drain channel of the filtering means is directly connected to the first inlet of CO<sub>2</sub> removing means. Davidner et al teach a blood treatment device comprising a blood filter (106) with a drain channel (158) for ultrafiltrate connected to a blood inlet of oxygenator (104) i.e. CO<sub>2</sub> removing means via 109, 111, 161 to provide diluent to blood (see paragraphs 0029-0030, 0034-0035, 0038). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the blood treatment device of Porro et al to connect a drain channel of the filtering means to the first inlet of CO<sub>2</sub> removing means to provide ultrafiltrate as a diluent to blood to reduce hematocrit as suggested by Davidner et al (see paragraph 0029). Recitation of “to supply the diluting liquid without submitting the diluting liquid to any filtering treatment during passage along the drain channel” is an intended use of the apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).



Porro et al further teaches that oxygenator (B1) and the hemoconcentrator (A1) are housed in respective separate casings that are joined and fixed rigidly to each other (see Fig. 7-8).

Claim 14 essentially differ from the device of Porro et al in view of Davidner et al in reciting CO<sub>2</sub> removing means comprising an inner seat housing filtering means and a first casing housing a number of membranes for removing CO<sub>2</sub>, the filtering means comprising a second casing housed inside the first casing and housing blood purifying membranes, and a container interposed between the membranes for removing CO<sub>2</sub> from blood. Linker et al teach a blood treatment device having a compact size and low surface area and reducing contact between the blood and foreign surfaces to reduce priming volume, hemolysis and platelet activation (see paragraph 0010). To achieve such compact blood treatment device, Linker et al teach a housing structure including CO<sub>2</sub> removing means (70) comprising an inner seat (see central shoulder section at the bottom of filter (59) in Fig. 3) housing filtering means, filtering means (59) comprising a second casing (see casing holding filter (59) in Fig. 3) housed inside the first casing (see outer casing in Fig. 3) and housing membranes (59), membranes (70) for removing CO<sub>2</sub> interposed between the first and second casing and a container (see central shoulder section at the bottom of filter (59) in Fig. 3) interposed between the membranes for removing CO<sub>2</sub> (70) and the second casing (see casing holding filter (59)) and internally defining the inner seat (see 0048-0053, 0055-0058). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the blood treatment device of Porro et al in view of Davidner et al to include above claimed structures to integrate known blood oxygenators, blood pumps and blood filters into a single housing as suggested by Linker et al (see paragraph 0048) and make

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the device compact having low surface area to reduce priming volume, hemolysis and platelet activation (see paragraph 0010).

8. Applicant's arguments with respect to claims 1-11, 13-14 and 25 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that neither Porro nor Linker discloses or suggests at least one drain channel being connected to the first inlet of CO<sub>2</sub> removing means. However, Davidner et al is applied to show that a drain channel of the a blood filter (106) e.g. filtering means (106) is connected to the first inlet of oxygenator (104) e.g. CO<sub>2</sub> removing means to provide ultrafiltrate as a diluent to blood to reduce hematocrit as suggested by Davidner et al (see paragraph 0029).

In response to applicant's argument that Davidner et al reference is nonanalogous art as pertaining to a method and apparatus for retroperfusing cerebral venous vasculature with autologous venous blood, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Davidner et al teaches a blood treatment unit comprising a blood filter (106) e.g. filtering means (106) is connected to the first inlet of oxygenator (104) e.g. CO<sub>2</sub> removing means.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. This application contains claims 21-24 drawn to an invention nonelected by constructively electing Group I (original claims 1-14) by original presentation as described in above paragraph 1. Complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/John Kim/  
Primary Examiner  
Art Unit 1797**

JK  
10/29/07